

BABO BABY FACE MINERAL SUNSCREEN- mineral sunscreen stick
Babo Botanicals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

8065 Babo Baby Face SPF 50 Mineral Sunscreen Stick

Principal Display Panel

Baby Face Mineral Sunscreen

Sheer & Gentle

Broad Spectrum SPF 50

70% Organic Ingredients

Water Resistant (80 Minutes)

Zinc Oxide Mineral Sunscreen

Fragrance Free

Net Wt 0.6 oz / 17 g

DRUG FACTS PANEL

Drug Facts Panel

Active Ingredient

Active Ingredient: Zinc Oxide Purpose: Sunscreen

Purpose

Sunscreen

Use

Helps prevent sunburn | If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only. | Do not use on damaged or broken skin. | When using this product Keep out of eyes. Rinse with water to remove. | Stop use and ask doctor if rash occurs. | Keep out of reach of children. If swallowed get medical help or contact a Poison Control center right away. May stain some fabrics and surfaces.

Keep Out of Reach of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Apply liberally to exposed areas 15 minutes before sun exposure. **Children under 6 months: Ask a doctor.**
- Reapply:
 - after swimming or sweating
 - immediately after towel-drying
 - at least every 2 hours
- **Sun Protection Measures** • Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other protection measures including: Limit time in the sun, especially from 10 a.m. – 2 p.m. and wear long-sleeve shirts, pants, hats, and sunglasses.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Oryza Sativa (Rice) Bran Oil*, Persea Gratissima (Avocado) Oil*, Euphorbia Cerifera (Candelilla) Wax, Octyldodecyl Olivat, Simmondsia Chinensis (Jojoba) Seed Oil*, Beeswax*, Theobroma Cacao (Cocoa) Seed Butter*, Oryzanol, Jojoba Esters, Butyrospermum Parkii (Shea) Butter*, Calendula Officinalis Flower Extract*, Chamomilla Recutita (Matricaria) Flower Extract*, Nasturtium Officinale (Watercress) Flower/Leaf Extract*, Spiraea Ulmaria (Meadowsweet) Flower Extract*, Bisabolol*, Calophyllum Inophyllum (Tamanu) Seed Oil*, Helianthus Annuus (Sunflower) Seed Oil*, Tocopherol (Vitamin E).

*Certified Organic Ingredients

Distributed by

Dist: by Babo Botanicals, Inc.
60 East 56th Street New York, NY 10022

Package Labeling



BABO BABY FACE MINERAL SUNSCREEN

mineral sunscreen stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.267 g in 100 g

Inactive Ingredients				
Ingredient Name			Strength	
TAMANU OIL (UNII: JT3LVK84A1)			0.01 mL in 100 g	
JOJOBA OIL (UNII: 724GKU717M)			7.5 mL in 100 g	
TOCOPHEROL (UNII: R0ZB2556P8)			0.75 mL in 100 g	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)			0.833 mL in 100 g	
ORYZANOL (UNII: SST9XCL51M)			3 mL in 100 g	
WHITE WAX (UNII: 7G1J5DA97F)			6 mL in 100 g	
CHAMOMILE (UNII: FGL3685T2X)			0.0005 mL in 100 g	
LEVOMENOL (UNII: 24WE03BX2T)			0.2 mL in 100 g	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)			0.0005 mL in 100 g	
CANDELILLA WAX (UNII: WL0328HX19)			9.5 mL in 100 g	
SHEA BUTTER (UNII: K49155VL9Y)			1 mL in 100 g	
RICE BRAN OIL (UNII: LZ06K1506A)			24.09 mL in 100 g	
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)			8.75 mL in 100 g	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)			0.0005 mL in 100 g	
COCOA BUTTER (UNII: 512OYT1CRR)			3 mL in 100 g	
CALOPHYLLUM TACAMAHACA SEED OIL (UNII: 05G85L61OE)			0.01 mL in 100 g	
SUNFLOWER OIL (UNII: 3W1JG795YI)			0.098 mL in 100 g	
AVOCADO OIL (UNII: 6VNO72PFC1)			15 mL in 100 g	
NASTURTIUM OFFICINALE FLOWERING TOP (UNII: W1N2U8I64G)			0.0005 mL in 100 g	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8065-1	1 in 1 CARTON	11/01/2020	
1		17 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M020	11/01/2020	

Labeler - Babo Botanicals, Inc. (058258734)